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| APPLICATION NO.                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/603,513                        | 06/24/2003  | Scott Gilbert        | ARC 3080 R1         |                  |
| 7590 06/28/2005                   |             |                      | EXAMINER            |                  |
| SAMUEL E WEBB<br>ALZ. CORPORATION |             |                      | MENDEZ, MANUEL A    |                  |
| C/O PUNSON & JOHNSON              |             |                      | ART UNIT            | PAPER NUMBER     |
| ONE JOHNSON & JOHNSON PLAZA       |             |                      | 3763                |                  |

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No.           | Applicant(s)                      |        |  |  |  |
|---|---|---------------------------|-----------------------------------|--------|--|--|--|
| Office Action Summary   |   | 10/603,513                | GILBERT ET AL.                    |        |  |  |  |
|   |   | Examiner                  | Art Unit                          |        |  |  |  |
|   |   | Manuel Mendez             | 3763                              |        |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |   |                           |                                   |        |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                           |                                   |        |  |  |  |
| Status  |   |                           |                                   |        |  |  |  |
| 1) Responsive to communic   | 1) Responsive to communication(s) filed on  |                           |                                   |        |  |  |  |
| 2a) ☐ This action is FINAL.   |   | action is non-final.      |                                   |        |  |  |  |
| ·— ··   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |                           |                                   |        |  |  |  |
| Disposition of Claims   |   |                           |                                   |        |  |  |  |
| 4) ☐ Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-26 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or election requirement.  |   |                           |                                   |        |  |  |  |
| Application Papers  |   |                           | •                                 |        |  |  |  |
| 9) The specification is object  | ed to by the Examiner   | •                         |                                   |        |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |   |                           |                                   |        |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                           |                                   |        |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                           |                                   |        |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                           |                                   |        |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |                           |                                   |        |  |  |  |
|   |   |                           |                                   |        |  |  |  |
| Attachment(s)   |   |                           |                                   |        |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.   |   |                           |                                   |        |  |  |  |
| 3) Information Disclosure Statement(s) ( Paper No(s)/Mail Date  | -   | 5) Notice of In 6) Other: | formal Patent Application (PT<br> | O-152) |  |  |  |

Application/Control Number: 10/603,513

Art Unit: 3763

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by **Bechtold et al.**, **Wyrick**, **or Holman**, **et al.** The cited patents disclose a housing, a reservoir for containing a medicament, a needle for delivering medicament, and a drive mechanism capable of exerting a force to expel the medicament from the reservoir through the

Art Unit: 3763

needle, the drive mechanism having various springs which inherently have shape memory.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bechtold et al., Wyrick, or Holman, et al., in view of Smoliarov et al., Cheikh, and Imran.

The examiner of record has included the Smoliarov et al., patent to demonstrate the conventionality of using drive springs that have shape transformation in its austenite and martensite states according to a particular temperature application. The examiner would also like to point out for the record, that the disclosed temperature ranges are considered intended uses that do not add any patentable weight to the claims in question. Accordingly, for a person of ordinary skill in the art, modifying the injectors disclosed by **Bechtold et al., Wyrick, or Holman, et al., with** drive springs that have shape transformation in its austenite and martensite states according to a particular temperature application would have been considered obvious in view of the conventionality of this particular enhancement.

Art Unit: 3763

The examiner has included **Cheikh and Imran** in the rejection to further demonstrate that the use of springs having shape memory characteristics is well known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Manuel Mendez Primary Examiner Art Unit 3763

MM